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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/714,253

11/14/2003

Victor I. Sementchenko

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06/26/2006

AFFYMETRIX, INC

ATTN: CHIEF IP COUNSEL, LEGAL DEPT.

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SANTA CLARA, CA 95051

EXAMINER

STRZELECKA, TERESA E

ART UNIT

PAPER NUMBER

1637

DATE MAILED: 06/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/714,253

Applicant(s)

SEMENTCHENKO ET AL.

Examiner

Teresa E. Strzelecka

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities: on page 9, line 20, Applicants cite a PCT application without the publication number.

Appropriate correction is required.

Claim Interpretation

2. The term “sample” has not been defined by Applicants, therefore it is considered as either a whole organism, an organ, tissue or cells.
3. The term “differentiation stage” has not been defined by Applicants, therefore it is considered as any state of a sample.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-5 are rejected under 35 U.S.C. 102(a) as being anticipated by Tamayo et al. (U.S. 2002/0115070 A1) as evidenced by Rava et al. (U.S. Patent No. 5,874,219 A).

Regarding claim 1, Tamayo et al. teach a method of transcriptional profiling comprising:

subjecting a biological sample to an exogenous stimulation (Tamayo et al. teach subjecting cells to external stimuli (page 1, [0004] and [0007]; page 3, [0025]; page 7, [0055]));

measuring transcriptional activity of the biological sample at a first differentiation stage (Tamayo et al. teach measuring transcriptional activity at 0.5 hour after stimulation with TPA, which results in cell differentiation (page 8, [0066]));

measuring transcriptional activity of the biological sample at a second differentiation stage (Tamayo et al. teach measuring transcriptional activity at 4 hours after stimulation with TPA, which results in cell differentiation (page 8, [0066])); and

comparing the transcriptional activities from the first and second differentiated stages in at least 5 Mbases, 50 Mbases or 100 Mbases of the genome to obtain a transcription profile (Tamayo et al. teach comparing the transcriptional profile at the different time points (page 8, [0066]-[0069]; page 9; page 10, [0079]). Since Tamayo et al. teach using total mRNA as a source for hybridization (page 7, [0057]), they inherently teach detecting transcriptional activities from all of the cells genomes, i.e. about 3×10^9 bp, anticipating the limitations of at least 5 Mbases, 50 Mbases or 100 Mbases of the genome).

Regarding claim 2, Tamayo et al. teach using mRNA for hybridization (page 3, [0026]) and probe (= oligonucleotide) arrays (page 3, [0027]).

Regarding claims 3-5, Tamayo et al. teach probe arrays of U.S. Patent No. 5,874,219 (page 3, [0027]) of Rava et al. Rava et al. teach oligonucleotide arrays with at least 1,000,000 probes, therefore Tamayo et al. anticipate the limitations of at least 100,000, at least 500,000 and at least 1,000,000 probes.

6. Claims 1-5 are rejected under 35 U.S.C. 102(e) as being anticipated by Tamayo et al. (U.S. 2002/0115070 A1) as evidenced by Rava et al. (U.S. Patent No. 5,874,219 A).

Regarding claim 1, Tamayo et al. teach a method of transcriptional profiling comprising:
subjecting a biological sample to an exogenous stimulation (Tamayo et al. teach subjecting

cells to external stimuli (page 1, [0004] and [0007]; page 3, [0025]; page 7, [0055]).);

measuring transcriptional activity of the biological sample at a first differentiation stage (Tamayo et al. teach measuring transcriptional activity at 0.5 hour after stimulation with TPA, which results in cell differentiation (page 8, [0066])).);

measuring transcriptional activity of the biological sample at a second differentiation stage (Tamayo et al. teach measuring transcriptional activity at 4 hours after stimulation with TPA, which results in cell differentiation (page 8, [0066])).); and

comparing the transcriptional activities from the first and second differentiated stages in at least 5 Mbases, 50 Mbases or 100 Mbases of the genome to obtain a transcription profile (Tamayo et al. teach comparing the transcriptional profile at the different time points (page 8, [0066]-[0069]; page 9; page 10, [0079]; Fig. 4 A-L). Since Tamayo et al. teach using total mRNA as a source for hybridization (page 7, [0057]), they inherently teach detecting transcriptional activities from all of the cells genomes, i.e. about 3×10^9 bp, anticipating the limitations of at least 5 Mbases, 50 Mbases or 100 Mbases of the genome).

Regarding claim 2, Tamayo et al. teach using mRNA for hybridization (page 3, [0026]) and probe (= oligonucleotide) arrays (page 3, [0027]).

Regarding claims 3-5, Tamayo et al. teach probe arrays of U.S. Patent No. 5,874,219 (page 3, [0027]) of Rava et al. Rava et al. teach oligonucleotide arrays with at least 1,000,000 probes, therefore Tamayo et al. anticipate the limitations of at least 100,000, at least 500,000 and at least 1,000,000 probes.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1637

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 6-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tamayo et al. (U.S. 2002/0115070 A1), as evidenced by Rava et al. (U.S. Patent No. 5,874,219 A), and Lockhart et al. (U.S. Patent No. 6,040,138 A).

A) Regarding claims 6 and 7, Tamayo et al. teach high-density oligonucleotide arrays, but do not teach mismatch probes.

Regarding claim 8, Tamayo et al. teach the cells being responsive to stimulation (page 8, [0066]-[0069]; page 9; page 10, [0079]; Fig. 4 A-L).

Regarding claim 9, Tamayo et al. teach that HL-60 is a tumor-derived cell line (page 8, [0066]).

B) Regarding claims 6 and 7, Lockhart et al. teach high density oligonucleotide arrays for transcriptional profiling (Abstract) which contain perfect match and mismatch probes, with a mismatch located in the center of the probe (col. 2, lines 35-55; col. 3, lines 30-38; col. 7, lines 21-34; col. 16, lines 62-67; col. 17, lines 1-27).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to have used the mismatch probes of Lockhart et al. in the method of transcriptional profiling on arrays of Tamayo et al. The motivation to do so, provided by Lockhart et al., would have been that the mismatch probes provided a control for non-specific binding and cross-hybridization and the difference in intensity between perfect match and mismatch probes provided a measure of hybridization material concentration (col. 17, lines 15-27).

9. No claims are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teresa E. Strzelecka whose telephone number is (571) 272-0789. The examiner can normally be reached on M-F (8:30-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Teresa Strzelecka
6/23/06

Teresa E Strzelecka
Primary Examiner
Art Unit 1637